

**RESULTS OF INVESTIGATION:** The article in the boxes was repacked from bulk stock shipped as described above.

**LIBELED:** 7-22-59, S. Dist. Calif.

**CHARGE:** 501(c)—while held for sale, the strength of the article differed from that which it was represented to possess, namely, ascorbic acid (drum label) 30 milligrams, and (box label) 100% minimum daily requirement in each capsule; 502(a)—the label statements (bulk drum) "Each capsule contains \* \* \* ascorbic acid (as sodium ascorbate) 30 mg." and (box label) "Each capsule contains \* \* \* Vitamin C (ascorbic acid) 100% minimum daily requirement" were false and misleading as applied to a product which contained little if any ascorbic acid; and the box label of the article contained false and misleading representations that the article was adequate and effective to prevent and to stop hangover and to restore perfect balance to the system.

**DISPOSITION:** 9-16-59 and 9-22-59. Default—delivered to the Food and Drug Administration.

### **DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS**

#### **DRUGS FOR HUMAN USE**

**5990. Cernelle Pollen tablets.** (F.D.C. No. 42893. S. No. 40-252 P.)

**QUANTITY:** 210 100-tablet btls. at San Francisco, Calif.

**SHIPPED:** 8-29-58, from Winter Park, Fla., by Cernelle Pollen Co.

**LABEL IN PART:** (Btl.) "A Concentrated Food Cernelle Pollen Tablets Imported from Sweden Pure Special Treated Pollen High in Amino Acids, Natural Vitamins and Minerals \* \* \* 1-3 Tablets daily \* \* \* Cernelle Pollen Co. Winter Park, Florida"; (btl. top) "Cernelle Pollen Vegeholm Sweden."

**ACCOMPANYING LABELING:** Circulars entitled "Cernelle Pollen Tablets."

**LIBELED:** 3-24-59, N. Dist. Calif.

**CHARGE:** 502(a)—when shipped and while held for sale, the labeling accompanying the article contained false and misleading representations that the article was an adequate and effective treatment to maintain general well-being; to delay the arrival of old age and to keep the body young and virile; to prevent diseases; to purify the blood; and that the article was effective as a laxative and rejuvenator; to develop sound muscles, bones, blood and glands; to better body functions, to produce uncommon vitality; and to cure cancer.

The libel also charged that the article was misbranded under the provisions of the law applicable to foods as reported in notices of judgment on foods.

**DISPOSITION:** 5-5-59. Default—destruction.

**5991. Mill Rue tonic.** (F.D.C. No. 41641. S. No. 11-294 P.)

**QUANTITY:** 196 8-oz. btls. at Bluffton, Ind.

**SHIPPED:** On or about September, 1957, from Carlock, Ill., by Roy Paxton.

**LABEL IN PART:** "MILL RUE TONIC HEMATINIC STOMACHIC \* \* \* EACH FLUID OUNCE SUPPLIES \* \* \* MALLOW HERB \* \* \* 5.6 GM (60 GR.) FERRIC AMMONIUM CITRATE 4.95 GR. VITAMIN B<sub>1</sub> \* \* \* 5.69 MG VITAMIN B<sub>2</sub> \* \* \* 3.14 MG. NIACINAMIDE 6.0 MG."

ACCOMPANYING LABELING: Brochures entitled "Why Suffer, Take Mill Rue and Enjoy Life as You Live."

LIBELED: 3-28-58, N. Dist. Ind.

CHARGE: 502(a)—when shipped, the labeling accompanying the article contained false and misleading representations that the article was an adequate and effective treatment for cancer, ulcers, kidney and bladder troubles.

DISPOSITION: 6-12-58. Default—25 bottles of the article and 25 copies of the brochure were delivered to the Food and Drug Administration and the remainder of the article and the brochure were destroyed.

5992. Ketovite tablets and Bioplete tablets. (F.D.C. No. 43163. S. Nos. 53-058/9 P.)

QUANTITY: 20,000 tablets in bulk container, 28 100-tablet btl., 60 200-tablet btl., 72 400-tablet btl., and 6 1,000-tablet btl. of Ketovite; and 10,000 tablets in bulk container; 17 180-tablet btl., and 30 360-tablet btl. of Bioplete at Los Angeles, Calif., in possession of Professional Foods.

SHIPPED: 3-22-59 (Ketovite), and 4-1-59 (Bioplete), from Cedar Rapids, Iowa, by Professional Foods.

LABEL IN PART: (Btl.) "Ketovite \* \* \* A Dietary Supplement made from Liver and other Meats (dessicated), Milk Solids, Rice Bran, Wheat Germ, Fractions from Wheat Germ, Rice Bran and Soya Oils, Amino Acids, Extracted Proteins, Alfalfa and Cereal Grain Juice Concentrates, Diastase, Enzymes, Vitamins and Minerals from Food Sources. \* \* \* Distributed by Professional Foods, Cedar Rapids, Iowa," and "Bioplete A Dietary Supplement, made from Liver and other Meats (dessicated), Milk Solids, Rice Bran, Wheat Germ, Fractions from Wheat Germ, Rice Bran and Soya Oils, Amino Acids, Extracted Proteins, Alfalfa and Cereal Grain Juice Concentrates, Diastase, Enzymes, Vitamins and Minerals from Food Sources. \* \* \* Distributed by Micro-Nutrients, 219 2nd Ave., S.W., Cedar Rapids, Iowa."

ACCOMPANYING LABELING: (For Ketovite) booklets entitled "The Facts About a Four-Way Product!" and leaflets entitled "For Your Well Being!—Ketovite"; and (for Bioplete) booklets entitled "Why You Need More!" and leaflets entitled "For Your Well Being!—Bioplete"; and a number of loose labels for Ketovite and Bioplete.

RESULTS OF INVESTIGATION: The articles were shipped in bulk from Iowa and were repacked and relabeled by the dealer. Literature was sent from Iowa at the request of the dealer.

LIBELED: 6-2-59, S. Dist. Calif.

CHARGE: 502(a)—when shipped and while held for sale, the labeling of the articles contained false and misleading representations that the articles were adequate and effective for the treatment and prevention of common diseases due to a partial starvation even though regular, normal meals may be consumed; growing old; chronic fatigue; anxiety and worry; headaches, stomach upsets, insomnia, creaking and aching joints; body deterioration; debility and sickness; chronic sickness and organic degeneration; inadequate nerve function; lack of endocrine and enzyme output; improper teeth and bones; wearing out of the body; underdeveloped muscles of arms, legs, and heart; blocking of hormone formation of the anterior pituitary gland; insufficient insulin production; artery and heart disease; retarded mental development; cell starvation; lack of consciousness and vitality; arrested growth; collapse during hard work and worry of older people; failure to repair damaged parts